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S/N 09/743,516

Remarks

In the 19 December 2002 Office Action the Examiner states Applicants' claims are rejected under 35 USC 112 as not being enabling with respect to the issues of timing and dosing. The Examiner also questions whether the recited steps achieve the goal stated in the preamble relative to cell proliferative disorders.

After considering Applicants' arguments, the Examiner is not persuaded the meaning of the phrase "wound site" includes both a site where a wound exists, or a site where a wound is planned because they are not supported by evidence. Specifically, the Examiner states the evidence does not show:

that one of skill in the pertinent art would understand upon reading the instant specification that the "wound site" would embrace wounds yet to be made, e.g. surgical incisions, particularly when the specification fails to even mention using the claimed method ancillary to surgery. Pages 3-4.

Applicants respectfully traverse the rejection. One of skill in the art would understand that term "wound site" includes in its meaning both a site where a wound exists, or a site where a wound is planned (e.g. surgical incision) based on the plain meaning of the word "site" and its use in the specification. The word "site" refers to a past, present or future location of something. (See definition of Cambridge Dictionary attached) The term "site" is not defined in the specification, though use of the term "site" in the specification is consistent with its meaning as generally understood. On page 34 lines 10-14 Applicants state that "sites of transfection and control sites . . . were prepared," and that "transfection was carried out at each transfection site." These statements show the term "site" is used to designate the locations where transfection and control will be carried out and where transfection and control subsequently were carried out.

One of skill in the art reading the specification would find the word "site" in the phrase "wound site" to be consistent with the general use of the word "site," and to be consistent with the use of the word within the specification. Moreover, one of skill in the art would also understand the phrase "wound site" to be consistent with the example in

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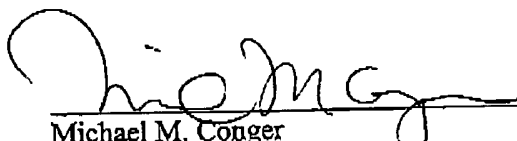
the specification which teaches that animals were prepared to receive wounds at a prepared site and subsequently received wounds at the prepared site.

Applicants request the rejection regarding the time when the nucleic acid is to be administered be withdrawn.

With respect to the rejections related to dosing and achieving the goal recited in the preamble, Applicants respectfully traverse in part the Examiner's rejections. The Examiner has maintained that the dosing ranges provided in the specification are insufficient to enable the claims. Applicants maintain that Applicants are not required to determine optimal dosing regimens for the various embodiments of the present invention. Moreover, determining specific dosing regimens in order to practice the invention would not require undue experimentation by one skilled in the art. Applicants have, however amended the preamble of the claims, which may help resolve the Examiner's concerns about dosing and achieving the goal recited in the preamble. Applicants request the rejection be reconsidered and withdrawn.

Applicants submit that the claims as amended are in condition for allowance and request favorable reconsideration.

Respectfully Submitted,

  
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